

PATENT APPLN. NO. 10/593,483  
SUBMISSION UNDER 37 C.F.R. § 1.114

**PATENT**

**REMARKS**

Claim 1 of the application has been amended to precisely recite the barrel of the pre-filled syringe of the present invention as having an axis extending from its tip to its open base end and to precisely define the axial length of the intermediate gasket and the axial length of the bypass as each being a length parallel to the axis of the barrel. Claim 8 has been similarly amended to define the axial length of a tip gasket, the axial length of the intermediate gasket and the axial length of the plunger gasket as each being a length parallel to the axis of the barrel.

The claims of the application as amended are believed to patentably distinguish over the syringe disclosed in Fig. 24 of Higashikawa relied upon by the Office in the 35 U.S.C. § 102 and 35 U.S.C. § 103(a) rejections of the claims of the application in the Final Action dated July 20, 2009.

First, regarding the limitation of the claims which requires the axial length of the intermediate gasket to be longer than the axial length of the bypass (as the axial lengths are defined in the claims), to function as a bypass in Higashikawa, the bypass groove 116 must necessarily be longer than the intermediate gasket 91. Gasket, or valve, 91 in Higashikawa includes a pair of annular lips

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at each end which are in contact with the inner surface of the cylinder straight portion 88 and seal the medicines in the cylinder. If the axial length of valve 91 is longer than the axial length of the bypass groove (parallel to the axis of the barrel, i.e., along the length of the barrel), the groove cannot act as a bypass because one set of annular lips will always be in contact with and seal the inner surface of the cylinder straight portion as the valve is advanced in the axial direction and passes the bypass groove. I.e., as the front set of annular lips advances beyond the opening of the bypass, the rear set of annular lips will be in contact with the inner surface of the cylinder and seal the cylinder and when the front set of lips reaches and advances beyond the closing of the bypass, the front set of lips will be in contact with the inner surface of the cylinder and seal the cylinder.

The bypass can only act as a bypass in Higashikawa if the axial length of the valve, or gasket, 91 is shorter than that of the bypass.

Therefore, the syringe of Higashikawa does not meet the limitation of the claims that the axial length of the intermediate gasket be longer than that of the bypass and cannot support the anticipation or obviousness of the claims.

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The syringe of Higashikawa also does not meet the limitation of claim 1 that when an axial length of the bypass is  $a_1$  and an axial effective length of the seal part is  $b_1$ ,  $a_1 > b_1$ . In Higashikawa, the seal part of the gaskets, e.g., valves 90 and 91, can only logically be interpreted as comprising both pair of annular lips at the ends of the valves. The seal part of the valves 90 and 91 cannot be properly construed as being only one pair of the annular lips.

The claims of the application are believed to be allowable over the prior art and a notice of allowability of the application is respectfully requested.

In the event that this paper is not considered to be timely filed, applicant hereby petitions for an appropriate extension of time. The fee for any such extension may be charged to our Deposit Account No. 111833.

In the event any additional fees are required, please also charge our Deposit Account No. 111833.

Respectfully submitted,  
KUBOVCIK & KUBOVCIK



Ronald J. Kubovcik  
Reg. No. 25,401

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Atty. Case No. NPR-192  
Crystal Gateway 3  
Suite 1105  
1215 South Clark Street  
Arlington, VA 22202  
Tel: (703) 412-9494  
Fax: (703) 412-9345  
RJK/ff